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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,411	01/16/2004	Elizabeth A. Gomez	03US7005	7477

23397 7590 02/27/2006

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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,411	GOMEZ ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-22* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15 and 17-22* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment, filed 12/1/05, is acknowledged and has been entered. Claim 16 has been canceled. Claims 1-15 and 17-22 are pending in the application, with claims 1-12 currently withdrawn.

Election/Restrictions

1. Applicant's confirmation of the election of Group III, claims 13-22 in the reply filed on 12/1/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicant's request for rejoinder of claims 6-12 is acknowledged (see Applicant's response, p. 9). However, as the product claims of Group III are not in condition for allowance, rejoinder is not appropriate at this time.

Specification

3. The abstract of the disclosure is objected to because the abstract as amended now discloses that the labeled intrinsic factor is bound to a solid phase, which does not represent the claimed invention. In the claimed invention, the **binding pair member** rather than the labeled intrinsic factor is bound to the solid phase. Correction is required. See MPEP § 608.01(b).

Claim Objections

4. Claim 13 is objected to because of the following informalities: the claim recites in part (c) "an interference blocking agent that will specifically bind to vitamin V12 in the sample, vitamin B12 being capable of binding...". The claim is objected to for grammatical reasons since

the above constitutes a run-on sentence. It is suggested that the sentence fragments be separated by a transitional word such as "wherein" (i.e., ...in the sample, **wherein** vitamin B12 **is** capable..."). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 13-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 13 recites the limitations "the binding site for the antibody" and "the autoantibody binding site of the labeled intrinsic factor" in parts b and c, respectively. There is insufficient antecedent basis for these limitations since the reference to the autoantibody site has been removed from part a of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 13-15, 17-18 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. (US Patent No. 6,942,977, filed May 28, 1993) or, alternatively, Newman et al. (Canadian Patent Application 2,110,109, Information Disclosure Statement filed 4/30/04) in view of Pourfarzaneh (US Patent No. 5,564,104). The column and line numbers cited below in reference to Newman et al. refer to the text of the US Patent.

Newman et al. teach diagnostic kits for assaying vitamin B12 comprising a receptor (intrinsic factor) that has a specific binding site for an autoantibody that directly blocks binding to vitamin B12 (column 1, lines 54-58) and a binding pair member capable of binding the receptor (antibody that specifically binds to intrinsic factor), wherein either the intrinsic factor or the antibody is labeled and one of them is immobilized on a solid support (column 4, lines 1-21). The antibody to intrinsic factor may be an antibody that is specific for the vitamin B12 binding site of intrinsic factor, and may be bound to a solid support (column 2, lines 8-22; column 2, line 63 to column 3, line 5; column 6, lines 12-17 in particular).

Newman et al. further teach extracting free vitamin B12 and other small molecular weight compounds from the sample using, for example, dextran coated charcoal (column 5, lines 23-36). However, Newman et al. fail to specifically teach an interference blocking reagent that will

specifically bind to vitamin B12 with higher binding affinity and/or specificity *than to any other moiety* (see the instant specification at [020]).

However, Pourfarzaneh teaches methods of removing labeled molecules from solution (column 2, lines 5-34 and Table A in particular). In particular, Pourfarzaneh teach that the molecules may be bound by binders such as charcoal adsorbents or monoclonal antibodies capable of binding the molecules (column 2, lines 20-34; column 8, lines 8-45 in particular). Examples of biological molecules that may be removed from solution include radiolabeled vitamin B12 (column 2, lines 14-16 in particular).

It would have been obvious to one of ordinary skill in the art to employ the monoclonal antibodies capable of binding to vitamin B12 taught by Pourfarzaneh in place of the dextran coated charcoal of Newman et al. in order to remove free vitamin B12 from samples containing antibodies to intrinsic factor, and because Newman et al. teach that removing free vitamin B12 is important in the identification of antibodies that will not be able to bind intrinsic factor or that will be released from binding in the presence of vitamin B12, which would be particularly difficult to detect if there were even trace amounts of vitamin B12 present (see Newman et al., the abstract and column 5, lines 23-36 in particular). One would have reasonable expectation of success because Pourfarzaneh teaches that both charcoal and monoclonal antibodies capable of binding to vitamin B12 may be used to remove molecules such as vitamin B12 from solution.

With regard to claims 14 and 21, Newman et al. teach that the solid support may be magnetic particles (column 6, lines 45-52).

With regard to claims 15 and 20, Newman et al. teach that the intrinsic factor may be labeled with alkaline phosphatase (column 8, line 30-47 and column 6, line 53 to column 7, line 3).

With regard to claim 22, Newman et al. teach that the anti-intrinsic factor antibody is a monoclonal antibody (the abstract and column 2, lines 8-11).

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. (US Patent No. 6,942,977) or, alternatively, Newman et al. (Canadian Patent Application 2,110,109) in view of Pourfarzaneh as applied to claims 13 above, and further in view of Herbert (US Patent No. 4,680,273). Newman et al. and Pourfarzeneh are as discussed above, which fail to specifically teach a test kit comprising **R-protein** as the interference blocking reagent.

Herbert teaches that R-protein is a binder for total corrinoids, including vitamin B12, which can be used to bind to vitamin B12 in solution (see column 4, in particular lines 58-62, and column 5, lines 1-42). R-protein may be used alone or in conjunction with the use of coated charcoal (column 5, lines 35-42).

Therefore, it would have been obvious to employ R-protein as the interference blocking reagent as taught by Herbert in the method of Newman et al. and Pourfarzaneh in order to remove free vitamin B12 from samples containing antibodies to intrinsic factor. One would have reasonable expectation of success in substituting R-protein for the monoclonal antibodies capable of binding vitamin B12 because Herbert teaches that R-protein are capable of binding vitamin B12, which is also the purpose of the charcoal and monoclonal antibodies taught by Newman et al. and Pourfarzaneh. In addition, Herbert teaches that R-protein may be used as a vitamin B12 binder in conjunction with coated charcoal methods, such as that of Newman et al.

Response to Arguments

The objections to the disclosure are withdrawn in response to Applicant's amendments.

The rejection of claim 13-22 under 35 USC 112, 1st paragraph are withdrawn in response to Applicant's amendments, in particular the amendment of claim 13 to recite "intrinsic factor" rather than "receptor" and "vitamin B12" rather than "substance".

With regard to the rejection of claims 13-16 and 20-22 under 35 USC 102(e) as being anticipated by Newman, Applicant's arguments and amendments have been fully considered and they are persuasive. Applicant argues (see p. 10-11 of Applicant's response) that the dextran-coated charcoal of Newman et al. cannot be considered to be an interference blocking reagent, since amended claim 13 requires that the interference blocking reagent will specifically bind to vitamin B12.

The specification defines specific binding as follows (see the specification at p. 6, [020]):

> As used herein, "specific binding" and "specifically bound" means that the reagent, substance or autoantibody is a binding pair member that binds or is bound to a desired substance or element with specificity, i.e., has a higher binding affinity and/or specificity to the substance or element *than to any other moiety.*" (emphasis added)

As a consequence of the above definition, claim 13 now requires that the interference blocking reagent bind with higher binding affinity and/or specificity to vitamin B12 *than to any other moiety.* The Examiner agrees that the dextran-coated charcoal of Newman et al. does not possess such a feature, and therefore the rejections of the claims as being anticipated by Newman et al. are withdrawn.

With regard to the rejection of claim 17-18 under 35 USC 103(a) as being unpatentable over Newman in view of Pourfarzaneh, Applicant's arguments have been fully considered but they are not persuasive. The references have been applied in the rejection of claims 13-15, 17-18

and 20-22 above under 35 USC 103(a). Applicant argues (p. 11-13) that Newman fails to disclose or suggest the use of an interference blocking reagent that is capable of specifically binding to vitamin B12. The Examiner maintains that while Newman fails to disclose a reagent that has higher binding affinity and/or specificity to vitamin B12 *than to any other moiety*, since the dextran coated charcoal has affinity with vitamin B12 and with other small molecular weight compounds, Newman clearly teaches the importance of removing free vitamin B12 from the sample at column 5, lines 23-36. While Newman does not specifically teach antibodies or monoclonal antibodies that are specific to vitamin B12 in order to achieve this, such a teaching is found in Pourfarzaneh, which teaches that either a charcoal absorbent (as in Newman) or a monoclonal antibody can be used to remove molecules from solution, which is the same purpose for which the charcoal is employed in Newman.

With regard to the rejection of claim 19 as being unpatentable over Newman in view of Pourfarzaneh, and further in view of Herbert, Applicant's response (p. 13) addressed the patentability of independent claim 13, which has been discussed above, but did not include any additional remarks regarding the specific limitation recited in claim 19 or the Herbert reference.

The rejections of the claims under 35 USC 103(a) as being unpatentable over Smith et al. are withdrawn in response to Applicant's amendments and arguments. In particular, the amendment to claim 13 to recite that the interference blocking reagent specifically binds to vitamin B12, discussed above with respect to the Newman et al. reference, is sufficient to overcome the rejections of the claims as being unpatentable over Smith et al. in view of Newman et al.

Conclusion

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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